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PATENT
Attorney Docket No.: JHU1680-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Germino et al.
Application No.: 09/904,968
Filed: July 13, 2001
Title: DETECTION AND TREATMENT OF POLYCYSTIC KIDNEY DISEASE

Art Unit: 1634
Examiner: S. Sakelaris

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL SHEET

Transmitted herewith for the above-identified application please find:

1. Response to Restriction Requirement mailed September 22, 2003 (3 pages);

2. Return receipt postcard.

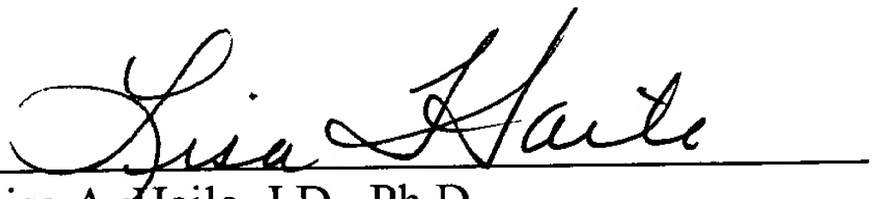
CERTIFICATION UNDER 37 CFR §1.8
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, **October 21, 2003**, in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.
Cara Grifone *(Name of Person Mailing Paper)*
Cara Grifone **October 21, 2003** *(Signature)* *(Date)*

Gray Cary\GT\6337708.1
104659-94

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge Deposit Account No. 50-1355.

Respectfully submitted,

Date: October 21, 2003



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RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This Reply is being filed in response to the Action mailed February 4, 2003, Paper No. 16 and further in response to the Communication dated September 22, 2003. The Examiner asserts that the Applicants were non-responsive in the reply filed on November 26, 2002 and the reply filed on March 6, 2003 for failing to elect the specific mutation detected by the elected method and for not selecting a mutation and corresponding primers

The requirement is being traversed for the reasons set forth in detail in the prior response and below.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, **October 21, 2003,** in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Cara Grifone
(Name of Person Mailing Paper)

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October 21, 2003
(Date)

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The Invention

The present invention relates generally to the diagnosis and treatment of polycystic kidney disease and more specifically to probes and agents useful in diagnosis and treatment of polycystic kidney disease and related disorders. The present invention provides oligonucleotide primers for the polymerase chain reaction (PCR) that selectively amplify regions of a PKD1 gene, but not its homologs and further provides oligonucleotide primers for nested PCR directed at selective amplification of regions of a PKD1 gene. The present invention further discloses methods for detection a wild type and mutant PKD1 gene and methods for identifying mutations within a PKD1 gene as well as its amplified regions. Additionally, the present invention relates to kits that utilize agents and methods of the present invention. The present invention also provides vectors and host cells containing the above-identified agents.

Applicants request that the elected species be examined, and, upon a finding that the elected species is allowable, that the entire scope of the claims be examined. Applicants hereby elect primers SEQ ID NOS: 3 and 4, nested primer pair SEQ ID NOS: 19 and 20, polynucleotides containing PDK1 mutations located in regions amplified by said nested primers, the methods of detecting this specific region with these specific nested primer pairs and kits containing these same primer pairs to amplify said specific region. The specific, elected mutation which can be identified by the elected method is the mutation wherein nucleotide 3666. Applicants note that nucleotide 3666 is in Exon 1, as noted in Table 1 of the specification and that the position of nucleotide 3666 would be amplified using the elected primers. The Examiner's confusion as to which exon position 3666 would be found stems from the fact that Table 1 lists the primers (based on genomic coordinates) vs. the patient mutations (usually based